NOV 1 5 2001 K012763

510(k) Summary

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Lynne Leonard
Phone:(303) 467-6586
Fax: (303) 467-6429

DATE PREPARED: August 16, 2001

DEVICE TRADE NAME: SORIN Biomedica SMAR$_x$T® BCD Vanguard™
Surface Modified Blood Cardioplegia System

COMMON/USUAL NAME: Cardioplegia Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Heat Exchanger

PREDICATE DEVICE: SORIN Biomedica BCD Vanguard™
Blood Cardioplegia System

DEVICE DESCRIPTION AND INTENDED USE:

The SMAR$_x$T BCD Vanguard is a cardioplegia heat exchanger with integral bubble trap, available with various tubing ratio configurations connected to the heat exchanger assembly. A surface-modifying material has been added to the primary blood contact surfaces of the heat exchanger to improve the blood compatibility of the device. The product is sterilized by ethylene oxide, is for single use only, and has nonpyrogenic fluid pathways.

The heat exchanger assembly (heat exchanger with bubble trap) contains a hydrophobic membrane, a one-way valve, a pressure relief valve, a filter screen, a temperature monitoring port and a pressure monitoring port. The housing is designed such that air entering the device rises to the membrane and is vented to the atmosphere. The one-way valve keeps air from entering the device. The pressure relief valve is designed to relieve excess pressure in the event of outlet line clamping, and has tubing attached to it to vent the solution to the cardiotomy reservoir. The temperature monitoring port is used to measure the temperature of the blood cardioplegia mixture, and the pressure monitoring line is connected to either a pressure manometer or a transducer to measure pressure.

INDICATIONS FOR USE

The SMAR$_x$T® BCD Vanguard™ Surface Modified Blood Cardioplegia System is intended to mix, cool, warm, and deliver oxygenated blood and cardioplegic solution for periods of up to six hours. The device also allows monitoring of temperature and pressure, traps bubbles, and removes air. Blood and cardioplegic solution are delivered to the patient by a single 100% occlusive roller pump, through the extension line and appropriate cannula.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The SMAR$_x$T® BCD Vanguard™ Surface Modified Blood Cardioplegia System has the same intended use as the SORIN® BCD Vanguard™ Blood Cardioplegia System. The two devices differ in that 1) the SMAR$_x$T® BCD Vanguard™ contains a surface-modifying material to improve blood compatibility; and 2) SMAR$_x$T Surface Modified Tubing and Connectors (K981613) are substituted for various tubing and connectors within the circuit configurations. Otherwise, materials, components, design, sterilization and manufacturing processes for the two devices are the same.

Biocompatibility testing and in-vitro testing were performed to demonstrate that the SMAR$_x$T® BCD Vanguard™ Surface Modified Blood Cardioplegia System is substantially equivalent to the currently marketed BCD Vanguard™ Blood Cardioplegia System.

In-vitro testing consisted of:

1. Stability testing, surface-modifying material
2. Surface-modifying material elution
3. Surface-modifying material blood compatibility
4. Heat exchanger efficiency
5. Priming volume
6. Blood pathway pressure drop
7. Blood pathway integrity
8. Ease of prime
9. Blood trauma (including platelet depletion, white blood cell depletion, and plasma free hemoglobin generation)
10. Connection integrity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2001

Mr. Lynne Leonard
Sr. Regulatory Affairs Manager
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K012763
Trade Name: Sorin Biomedica SMAR$_x$T BCD Vanguard Surface Modified Blood Cardioplegia System
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger.
Regulatory Class: Class II (two)
Product Code: DRT
Dated: August 16, 2001
Received: August 17, 2001

Dear Mr. Leonard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 5 2001

Indications For Use

510(k) Number (If known): K012763

Device Name: Sorin Biomedica SMAR$_x$T® BCD Vanguard™ Surface Modified Blood Cardioplegia System

Indications For Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory ...
510(k) Number K012763

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)